

## REMARKS

The amendments to the claims do not add new matter. The amendments to the claims are consistent with the disclosure in the specification and in the priority application USSN 08/920,630, filed 08/27/97, now abandoned. The Applicants deleted the specific recitation of “one or more,” “two or more” and “three or more” bone pins in favor of the more generic disclosures in USSN 08/920,630 of the plural term “bone pins” and the more specific disclosure of “4 bone pins.” The Patent Office has already acknowledged support for “four” bone pins stating “there are only 2 bone portions and **4 pins** set forth as the sole example in the parent application.” [Official Action at page 2, citing FIG. 7 and page 17.] Support for the undesignated plurality “bone pins” is found throughout the specification and is not so limited to “4” as shown in FIG. 7. See the specification of USSN 08/920,630 at page 5, lines 13-15 (“Such stacked implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein **appropriate retention pins** made from any desirable material, including **cortical bone**. . . .”); and at page 17, lines 10-12 (“**Pins**, composed of **cortical bone**, resorbable but strong biocompatible synthetic material, or metallic **pins** of the appropriate diameter are then impelled into the **holes** in the implants such that the implants are formed into a unitary body by these **pins**”); and at page 17, lines 25-28 (“The two halves may be implanted in juxtaposition, or **holes** may be formed in each half, and the halves maintained in contact by forcing **pins** through the holes, in a fashion analogous to that described above for maintaining **stacked** implants in contact with each other”); emphasis added in bold. Thus, the earliest claimed priority application, parent application, USSN 08/920,630, filed 08/27/97, has written description support for a **genus** of implants having a plurality of “holes” and “pins”, a **subgenus** of FIG. 8 (side by side) having “holes” and pins, a **subgenus** of stacked implants having “holes” and “pins”, and a **species** of FIG. 7A-7B having “four” holes and “four” appropriately sized pins. These latter species are now claimed in new claims 61 and 62.

Claim 27, which has been amended to recite that the pins are of “appropriate diameter,” is supported throughout the specification, including at page 17, lines 10-12 (“Pins, composed of cortical bone, resorbable but strong biocompatible

synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins.”).

Claim 33, which has been amended to recite that the implants are “stacked,” is supported throughout the specification, including at page 5, lines 13-15 (“Such **stacked** implants may be maintained in a unitary association by drilling appropriate holes through the height of the implant, and inserting therein **appropriate retention pins** made from any desirable material, including **cortical bone**. . . .”)

For all these reasons, the amendments to the claims do not add new matter.

### **Summary of the Bases for Objection /Rejection**

The Patent Office has assigned an effective filing date of 02/12/01 to claims 26-34.

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154.

Claim 29 is objected to as to its form.

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

Claims 26-31 and 33 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.).

Claims 26-28, 30, 31, 33 and 34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis).

Claims 26, 27, 31 and 33-34 are re rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,716,358 (Ochoa).

Claims 26-31 and 33-34 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,025,538 (Yaccarino).

Claim 32 is rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,025,538 (Yaccarino) alone.

Each of these nine bases for objection and/or rejection are addressed in Sections I-IX, respectively, which follow.

## I. Effective Filing Date of Claims 26-34

### “one or more”

The Patent Office contends that claims 26-34 are only entitled to the filing date of the present application—February 12, 2001. [Official Action at page 2.] Specifically, the Patent Office contends that “claims 26-31 and 33-34 have this date because of the ‘one or more . . . pins’, ‘two or more’ or ‘three’ connected bone portions in combination with bone pins. . . .” [Official Action at page 2.] According to the Patent Office, “there are only 2 bone portions and **4 pins** set forth as the sole example in the parent application.” [Official Action at page 2, citing FIG. 7 and page 17.] The Applicants respectfully submit that the priority application (USSN 08/920,630, filed 08/27/97) teaches the referenced Example, shown in FIG. 7, having 2 bone portions and 4 pins. However, the priority application also contains a generic teaching in words which supports a plurality of bone portions, which form a unitary construct using the **plural** designation of “**pins**” that are inserted in the corresponding **plural** designation “**holes**” Insofar as these generic terms (“pins” and “holes”) do not have the exact words “two or more” or “three or more” in front of them, the Applicants have amended the claims 26, 28, 31, 33 and 34, deleting the subgenus “one or more” and leaving the genus “pins.”

Support for the generic term “bone pins” is found throughout the specification of the priority application (USSN 08/920,630 ) and is not so limited to “4” as shown in the species of FIG. 7. See the specification of USSN 08/920,630 at page 5, lines 13-15 (“Such stacked implants may be maintained in a unitary association by drilling appropriate **holes** through the height of the implant, and inserting therein **appropriate retention pins** made from any desirable material, including **cortical bone**. . . .”); and at page 17, lines 10-12 (“**Pins**, composed of **cortical bone**, resorbable but strong biocompatible synthetic material, or metallic **pins** of the **appropriate diameter** are then impelled into the **holes** in the implants such that the **implants** [i.e., bone portions] are formed into a unitary body by these **pins**”); and at page 17, lines 25-28 relative to FIG. 8 (“The two halves may be implanted in juxtaposition, or **holes** may be formed in each half, and the halves maintained in contact by forcing **pins** through the holes, in a fashion analogous to that described above for maintaining **stacked** implants in contact with each other”); emphasis added in bold.

Thus, the earliest claimed priority application, parent application, USSN 08/920,630, filed 08/27/97, has written description support for the following: i) a **genus** of implants having a plurality of “holes” and “pins”; ii) a **subgenus** of FIG. 8 (side by side) having “holes” and pins; iii) a **subgenus** of stacked implants having “holes” and “pins”; and iv) a **species** of FIG. 7A-7B having two bone portions with “four” holes (each) and “four” appropriately sized pins. These latter species are now claimed in new claims 61 and 62.

For all these reasons, the claims 26-34 have written description support in claimed priority application USSN 08/920,630, filed 08/27/97 and are entitled to the claimed priority date of 08/27/97.

#### **“cancellous bone portion”**

The Patent Office also contends that claims 30 and 32 are only entitled to the present filing date (02/12/01) because “of the ‘**cancellous**’ bone portions where the implant constitutes two or more portions that have been connected together by press fitting.” [Official Action at page 2; emphasis added in bold.] The Applicants have amended claim 32, which originally recited that a “cancellous” bone portion was press fitted into a hole. As amended, claim 32 now recites that a “cortical bone pin” is press fitted in the hole. Accordingly, claim 32 has written support in priority application USSN 08/920,630, filed 08/27/97.

Separately, claim 30 recites as follows:

The assembled bone graft of claim 28, wherein said two or more connected, distinct, bone portions are selected from the group consisting of: **cortical bone and cancellous bone**.

The Applicants respectfully submit that the specification of priority application USSN 08/920,630, filed 08/27/97, discloses making a shaped implant of “cancellous” bone:

In figure 3B, there is provided an end-on view of the **cancellous bone plug 310** after the broaching procedure is completed. As can be seen, the internal canal 104 has been converted from a circular canal into a substantially **“D”-shaped canal**. As will be appreciated from this disclosure, any of a number of different asymmetric shapes in the internal canal 104 may be defined by this or analogous means, the principal goal being to provide a purchase

(referred to herein as a "key way") **within the implant** for external machining of the implant.

[USSN 08/920,630 at page 11, lines 7-13; emphasis added in bold.]

Thus, the priority application discloses the making and shaping of a "cancellous" "implant." Elsewhere, the priority application discloses the "stacking" of the previously disclosed "implants" (e.g., which includes the already disclosed cancellous implant):

In figure 7, there is shown a further aspect of this invention in which an **implant, either machined as described above**, or prior to said machining, is **further machined so as to allow stacking** thereof to achieve implants of various heights.

[USSN 08/920,630 at page 16, line 1 to page 17, line 2; emphasis added in bold.]

Thus, the priority application discloses the stacking of a plural number of "implants."

Finally, the specification discloses that these (plural) stacked "**implants**" are held together with pins, such as cortical bone pins:

. . . alternate methods of producing the implant of desired heights disclosed herein may be employed. For example, in a first such alternate method, **implants of this invention** are produced and then **stacked** to provide a **unitary implant** of the desired height dimensions. Such **stacked implants** may be maintained in a unitary association by drilling appropriate **holes** through the height of the implant, and inserting therein appropriate **retention pins** made from any desirable material, including cortical bone, bioabsorbable synthetic polymer, titanium or other metallic retention pins.

[[USSN 08/920,630 at page 5, lines 10-16; emphasis added in bold.]

Thus, priority application USSN 08/920,630, filed 08/27/97, discloses making a "unitary implant" from the shaped implants already disclosed which included an implant of figure 3 that was made from "cancellous" bone.

**“press fitting”**

In construing the “press-fit” limitation, the Patent Office stated that an “interference fit” and a “**snug fit**” (of the cited prior art) “is considered to be the same as a press fit.” [Official Action of 01/04/05 at page 3.] In response, the Applicants wish to point out that the present invention claims priority to USSN 08/920,630, filed 08/27/97, now abandoned. A copy of this specification is attached as Exhibit A of the Applicants’ Response to the Official Action of 11/04/03. This claimed priority application discloses the subject matter of claims 27 and 31-33, directed to an assembled implant comprising two cortical bone pieces that are held together by cortical bone pins that are press fitted into machined holes in the two cortical bone pieces:

**Pins, composed of cortical bone, resorbable but strong biocompatible synthetic material, or metallic pins of the appropriate diameter are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins.**

[USSN 08/920,630 at page 17, lines 10-12; emphasis added in bold.]

\* \* \*

In a further embodiment of this invention, shown in figure 8, a method for assembling the implant of this invention from component parts is provided. In figure 8A, there is shown an implant 800 composed of **two side-by-side halves**, 801A and 801B. The two halves of the implant are brought into juxtaposition to form a unitary implant. The two halves may be implanted in juxtaposition, or holes may be formed in each half, and the halves **maintained in contact by forcing pins through the holes**, in a fashion analogous to that described above **for maintaining stacked implants in contact with each other.**

[USSN 08/920,630 at page 17, lines 22-28; emphasis added in bold.]

Thus, the specification of Applicants’ claimed priority application does disclose “forcing” or “impelling” pins, i.e., press-fitting pins, into the holes in the two portions of the implant.

For all these reasons, claims 26-34 are entitled to the priority filing date of 08/27/97.

## **II. Obviousness Type Double Patenting**

Claims 26-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 79 of copending sister application USSN 09/941,154. However, no claims have been allowed in either application, and may be subject to amendment. Applicants will reconsider the issue at such time as it is ripe and claims become allowed in either application.

## **III. Objection as to Form**

Claim 29 is objected to as to its form. In particular, the Patent Office has suggested that the use of “comprising” is confusing, and suggested instead the use of “where there are.” [Official Action at page 3.] In response, the Applicants have amended claim 29 consistent with the Patent Office’s suggestion. Accordingly, this basis for objection has been rendered moot.

## **IV. 35 U.S.C. § 112, Second Paragraph (Indefiniteness)**

Claim 27 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. According to the Patent Office, the use of “said composite” in claim 27 lacks antecedent basis. In response, the Applicants have amended claim 27 by deleting the phrase “said composite” and replacing it with “said assembled” bone graft for which there is antecedent support. Accordingly, this basis for rejection of claim 27 has been rendered moot.

## **V. 35 U.S.C. § 102(e) over U.S. Pat. 6,200,347 (Anderson)**

Claims 26-31 and 33 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.). Anderson has an earliest claimed priority filing date of 01/05/99. Applicants have again amended claims 26-34 in conformity with the Applicants priority application USSN 08/920,630, filed 08/27/97. Moreover, in Section I herein, the Applicants have cited to those portions of Applicants’ claimed priority application USSN 08/920,630, filed 08/27/97, that support claims 26-31 and 33.

Accordingly, Anderson, which has an earliest claimed priority date of 01/05/99, is not prior art against the present claimed invention .

**VI. 35 U.S.C. § 102(b) over U.S. Pat. 5,147,367 (Ellis)**

Claims 26-28, 30-31 and 33-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis). According to the Patent Office, “Ellis anticipates the claim language where the bone pieces or bone portions of the same patient are grafted back **onto the bones they were separated from** to form a graft. . . .” [Official Action at page 4, citing Ellis at the figures, the abstract, and column 5, lines 12-56; emphasis added in bold.] Thus, in the bolded language above, the Patent Office acknowledges that Ellis discloses binding the bone back to its **original** location (*i.e.*, the location that it was “**separated from**”). As support for its position, the Patent Office cites to Stedman’s Medical Dictionary, 23<sup>rd</sup> Edition at page 599 for the definition of “graft” as “anything inserted into something else so as to become an integral part of the latter.” [Official Action at page 4.] However, the definition upon which the Patent Office relies misses the fine part of the definition which requires that the “anything” come from a “**different site or source**.” As support for the Applicants’ position, the Applicants cite to the following three medical dictionaries, including Stedman’s, as relied upon by the Patent Office, which did include the definition of “bone graft” as specifically recited in Applicants’ claims:

**graft** - a tissue or an organ taken from a site or a person and inserted into a **new site or person**, performed to repair a defect in structure.

[Exhibit A: Mosbey’s Medical, Nursing and Allied Health Dictionary, The C.V. Mosbey Co., St Louis, 1990, Eds. Glanze, et al., at page 531 ; emphasis added in bold.]

\* \* \*

**grafting** - The implantation of skin or other tissue, **from a different site or source**, to replace damaged tissue.

[Exhibit B: Dorland’s Illustrated Medical Dictionary, W.B. Saunders & Co., 24<sup>th</sup> Edition, Philadelphia, 1965, at page 629; emphasis added in bold.]



\* \* \*

**bone graft** - bone transplanted from a **donor site** to a **recipient site**.

[Exhibit C: Stedman's Medical Dictionary, 24<sup>th</sup> Edition, Williams & Wilkins, Baltimore, 1982, at page 604, emphasis added in bold.]

Thus, the art as a whole, including the dictionary relied upon by the Patent Office, recognizes that a "graft" is tissue that comes from a "**different site or source**." Accordingly, when Ellis discloses binding a fracture piece of bone back to its original location, it is not a "graft" because the broken piece of bone is not from a "**different site or source**" or from a "**donor site**," nor is it moving to a "**new site**." For all these reasons, claims 26-28, 30-31 and 33-34 are not anticipated by U.S. Pat. 5,147,367 (Ellis) under 35 U.S.C. § 102(b).

#### **VII. 35 U.S.C. § 102(b) over U.S. Pat. 5,716,358 (Ochoa)**

Claims 26, 27, 31 and 33-34 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,716,358 (Ochoa). According to the Patent Office, "Ochoa meets the claim language where the bone pieces or bone portions of the same patient are grafted back **onto the bones they were separated from** to form a graft. . . ." [Official Action at page 5, citing Ochoa at Figures 4 and 5, and column 6, line 57 to col. 8, line 47; emphasis added in bold.] In the bolded language above, the Patent Office acknowledges that Ochoa discloses binding the bone back to its **original** location (*i.e.*, the location that it was "**separated from**"). As support for its position, the Patent Office cites to Stedman's Medical Dictionary, 23<sup>rd</sup> Edition at page 599 for the definition of "graft" as "anything inserted into something else so as to become an integral part of the latter." [Official Action at page 5.] However, the definition upon which the Patent Office relies misses the fine part of the definition of "graft" which requires that the "anything" come from a "**different site or source**." As support for the Applicants' position, the Applicants cite to the following three medical dictionaries, including Stedman's, as relied upon by the Patent Office, which did include the definition of "bone graft" as specifically recited in Applicants' claims:

**graft** - a tissue or an organ taken from a site or a person and inserted into a **new site or person**, performed to repair a defect in structure.

[Exhibit A: Mosbey's Medical, Nursing and Allied Health Dictionary, The C.V. Mosbey Co., St Louis, 1990, Eds. Glanze, et al., at page 531; emphasis added in bold.]

\* \* \*

**grafting** - The implantation of skin or other tissue, **from a different site or source**, to replace damaged tissue.

[Exhibit B: Dorland's Illustrated Medical Dictionary, W.B. Saunders & Co., 24th Edition, Philadelphia, 1965, at page 629; emphasis added in bold.]

\* \* \*

**bone graft** - bone transplanted from a **donor site** to a **recipient site**.

[Exhibit C: Stedman's Medical Dictionary, 24<sup>th</sup> Edition, Williams & Wilkins, Baltimore, 1982, at page 604, emphasis added in bold.]

Thus, the art as a whole, including the dictionary relied upon by the Patent Office, recognizes that a "graft" is tissue that comes from a **"different site or source."** Accordingly, when Ochoa discloses binding a fractured piece of bone back to its **original** location, it is not a "graft" because the broken piece of bone is not from a **"different site or source"** or from a **"donor site,"** nor is it moving to a **"new site."** For all these reasons, claims 26, 27, 31 and 33-34 are not anticipated by U.S. Pat. 5,147,367 (Ellis) under 35 U.S.C. § 102(b).

#### **VIII. 35 U.S.C. § 102(e) over U.S. Pat. 6,025,538 (Yaccarino)**

Claims 26-31, and 33-34 are rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,025,538 (Yaccarino). Yaccarino has an earliest claimed priority filing date of 01/20/98. Applicants have again amended claims 26-34 in conformity with the Applicants priority application USSN 08/920,630, filed 08/27/97. Moreover, in Section I herein, the Applicants have cited to those portions of Applicants' claimed priority application USSN 08/920,630, filed 08/27/97, that support claims 26-31 and 33-34. Accordingly, Yaccarino, which has an earliest claimed priority date of 11/20/98 is not prior art against the present claimed invention.

## IX. 35 U.S.C. § 103(a) over U.S. Pat. 6,025,538 (Yaccarino)

Claim 32 is rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,025,538 (Yaccarino) alone. Yaccarino has an earliest claimed priority filing date of 01/20/98. The Applicants have amended claim 32, which originally recited that a “cancellous” bone portion was press fitted into a hole. As amended, claim 32 now recites that a “cortical bone pin” is press fitted in the hole. Support for “cortical bone pins” is found in Applicants’ priority application USSN 08/920,630, filed 08/27/97, at page 17, lines 10-12 (“**Pins**, composed of **cortical bone**, resorbable but strong biocompatible synthetic material, or metallic **pins** of the **appropriate diameter** are then impelled into the **holes** in the implants such that the **implants** [i.e., bone portions] are formed into a unitary body by these **pins**”); and at page 17, lines 25-28 relative to FIG. 8 (“The two halves may be implanted in juxtaposition, or **holes** may be formed in each half, and the halves maintained in contact by forcing **pins** through the holes, in a fashion analogous to that described above for maintaining stacked implants in contact with each other”); emphasis added in bold. Accordingly, claim 32 has written support in priority application USSN 08/920,630, filed 08/27/97. Therefore, Yaccarino, which has an earliest claimed priority date of 11/20/98 is not prior art against the present claimed invention.

## CONCLUSION

Claims 26-34 are pending and subject to rejection. Claims 61-62 have been added by amendment herein.

The Applicants have shown that claims 26-34 have an effective filing date of 08/27/97. The rejection of claims 26-34 under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Pat. 6,200,347 (Anderson et al.) or U.S. Pat. 6,025,538 (Yaccarino) have been rebutted. The rejection of claims 26-28, 30-31, and 33-34 under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,147,367 (Ellis) have been rebutted. The rejection of claims 26, 27, 31 and 33-34 under 35 U.S.C. § 102(b) for allegedly being anticipated by U.S. Pat. 5,716,358 (Ochoa) have been rebutted. The rejection of claim 32 under 35 U.S.C. § 103(a) for allegedly being unpatentable over U.S. Pat. 6,025,538 (Yaccarino) alone has been

rendered moot by the amendment herein. Finally, the above-recited bases for rejection should not be applied to newly submitted claims 61 and 62 for the reasons already provided herein.

Claims 26-34 and 61-62 are in condition for allowance. Their allowance is respectfully requested.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:

A handwritten signature in black ink, appearing to read "Donald J. Pochopien", written over a horizontal line.

Donald J. Pochopien

Registration No. 32,167

Attorney for Applicants

500 West Madison Street, 34<sup>th</sup> Floor

Chicago, Illinois 60661

(312) 775-8133

Date: July 15, 2005

J:\open\Djp\Regeneration Technologies\USPTO\13980US02\Resp 1.111 post RCE.doc